Trade in Pharmaceuticals and Medical Devices between the EU and Singapore - Opportunities under the EUSFTA and Beyond
Webinar

Medical devices, from innovation, selection, supply and management and the context with other health products

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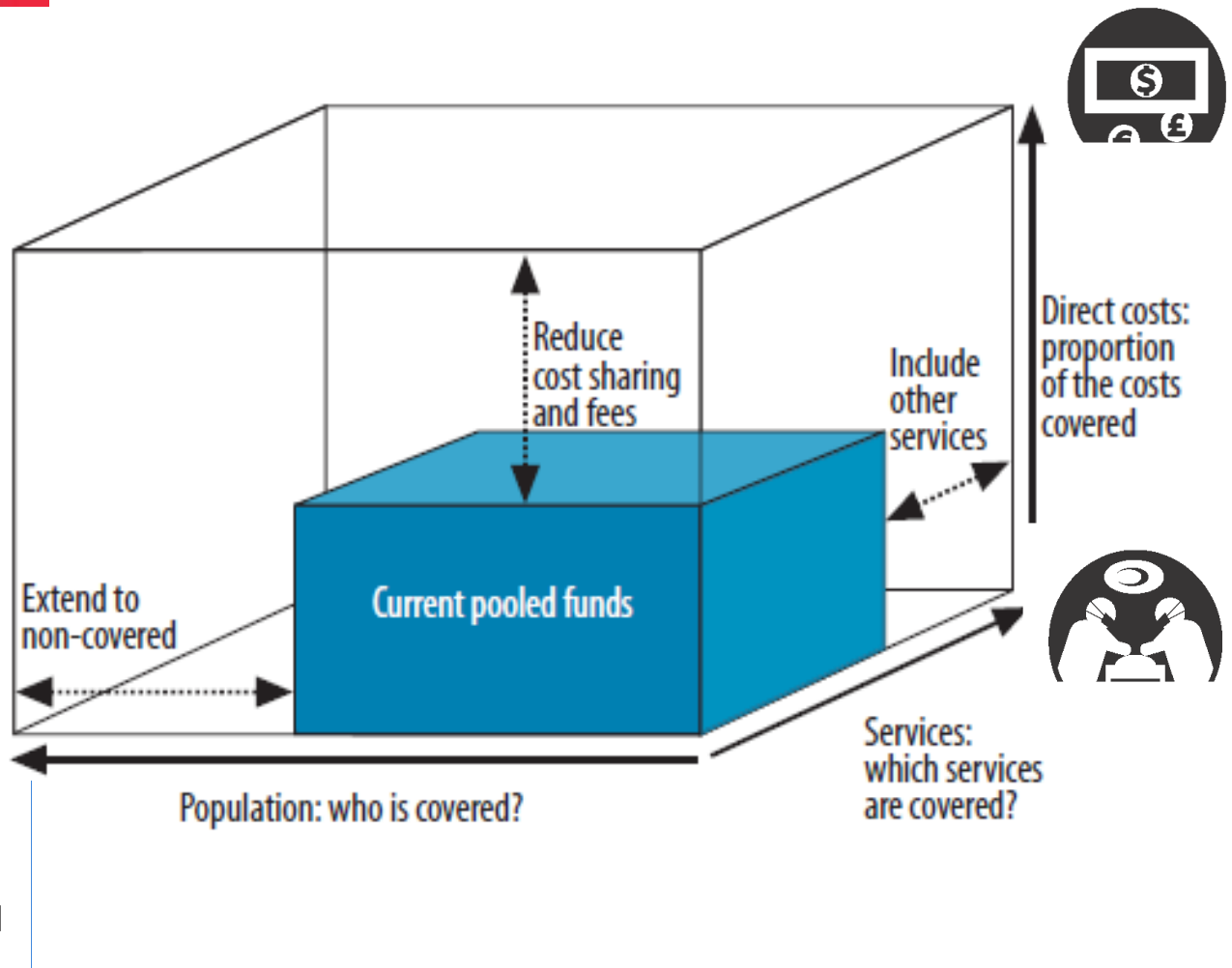
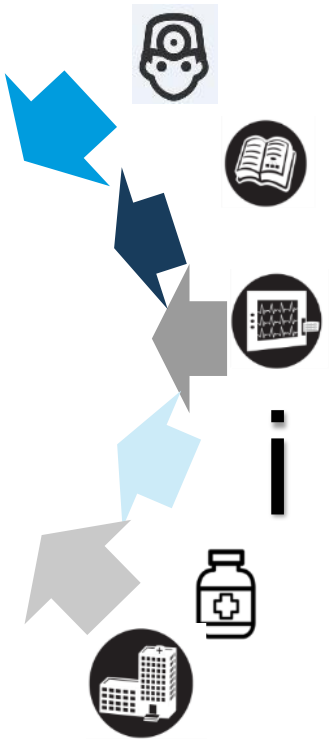
Goal 3. Good health and well being

SDG3: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services





To ensure improved access of safe, quality medical devices

R&D

» Industry and Academics: Research and development should be based on needs

Assessment

» Health Technology Assessment
» Lists of MD for reimbursement or procurement

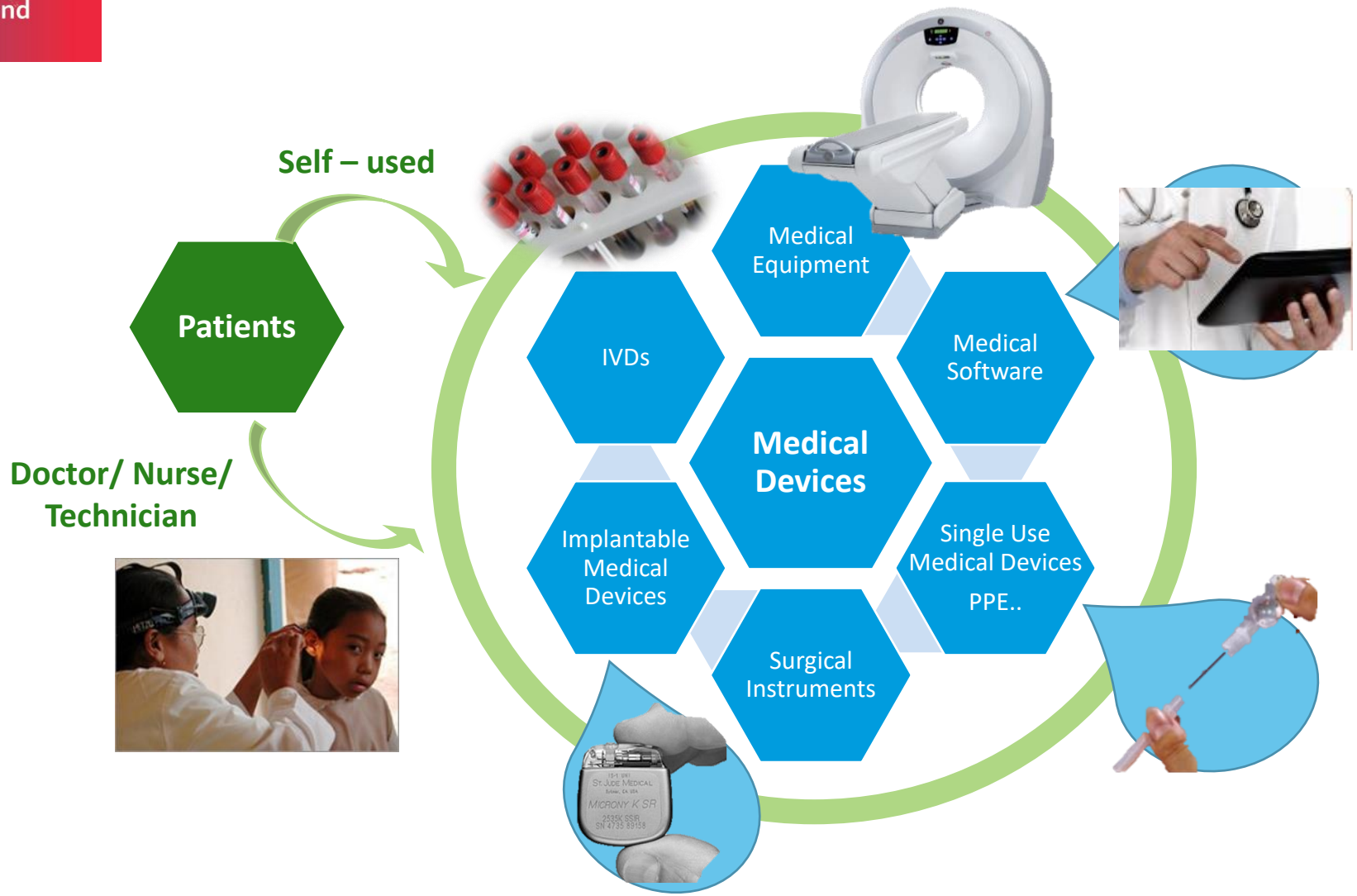
Regulations

» Regulation process of medical devices
» Lists of approved MD for marketing in country.

Management

» Procurement
» Installation, training, maintenance
» Safe use, operating costs and clinical effectiveness
» Post market surveillance and adverse event report
» Decommissioning, Replacement

Complementary tools for Medical Devices considering:



Sequence of process to ensure access to appropriate and safe health technologies

Health technology regulation

Safety

performance and quality

Health technology assessment

Clinical effectiveness

Ethics

Social issues

Organizational

Health technology management

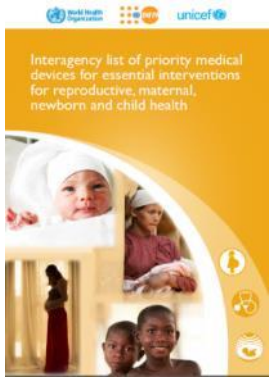
Procurement

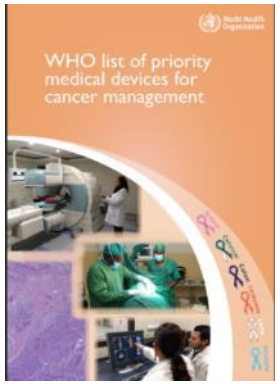
Selection

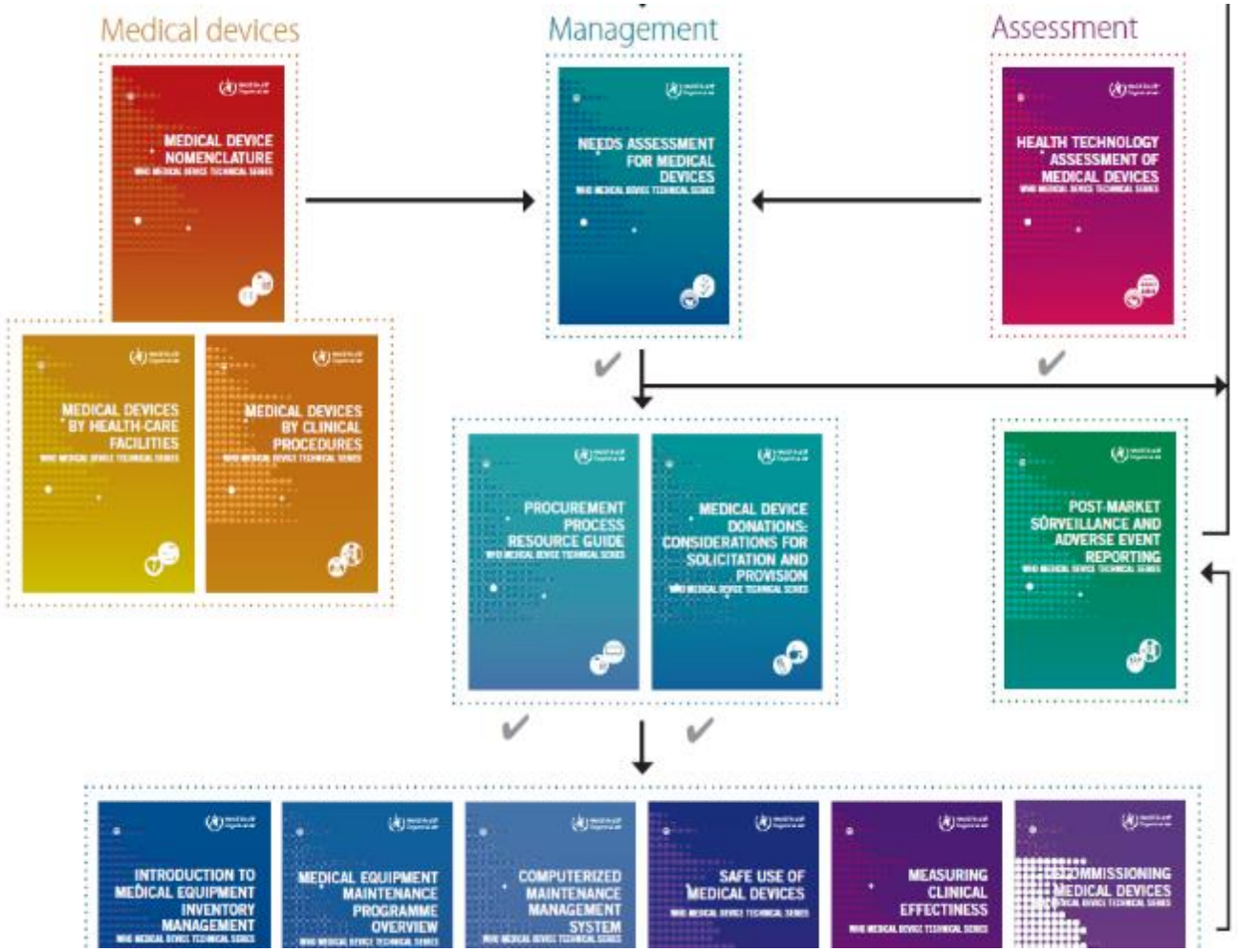
Training

Use

Health technology Assessment, Health technology management and lists of priority medical devices.







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WHO publishes guidance to Member States on all the topics: from innovation to post market surveillance.

https://www.who.int/health-topics/medical-devices#tab=tab_1

Innovative health technologies (2011, 2014, 2017, 2021)

Priority medical devices for: reproductive, maternal, newborn and child, Cancer cardiac diseases, stroke, diabetes (@3000 devices) (2015, 2017, 2021*)

Essential in vitro diagnostic List (EDL) @200 tests. (2021)

Model Regulatory Framework for medical devices including IVDs. (2017)

guidance for Post market surveillance (2020)

e-EDL and Priority Medical Devices Information System (clearinghouse) (2021*)

Procurement, donations, maintenance, decommissioning guidance (several publications 2011 to 2020)

Priority medical devices for COVID-19 and associated technical specifications for procurement (2020)

Technical specifications for personal protective equipment (2020)

https://www.who.int/health-topics/medical-devices#tab=tab_1

Regulatory systems for medical products

Harmonization, reliance, and regional sharing of information is welcome

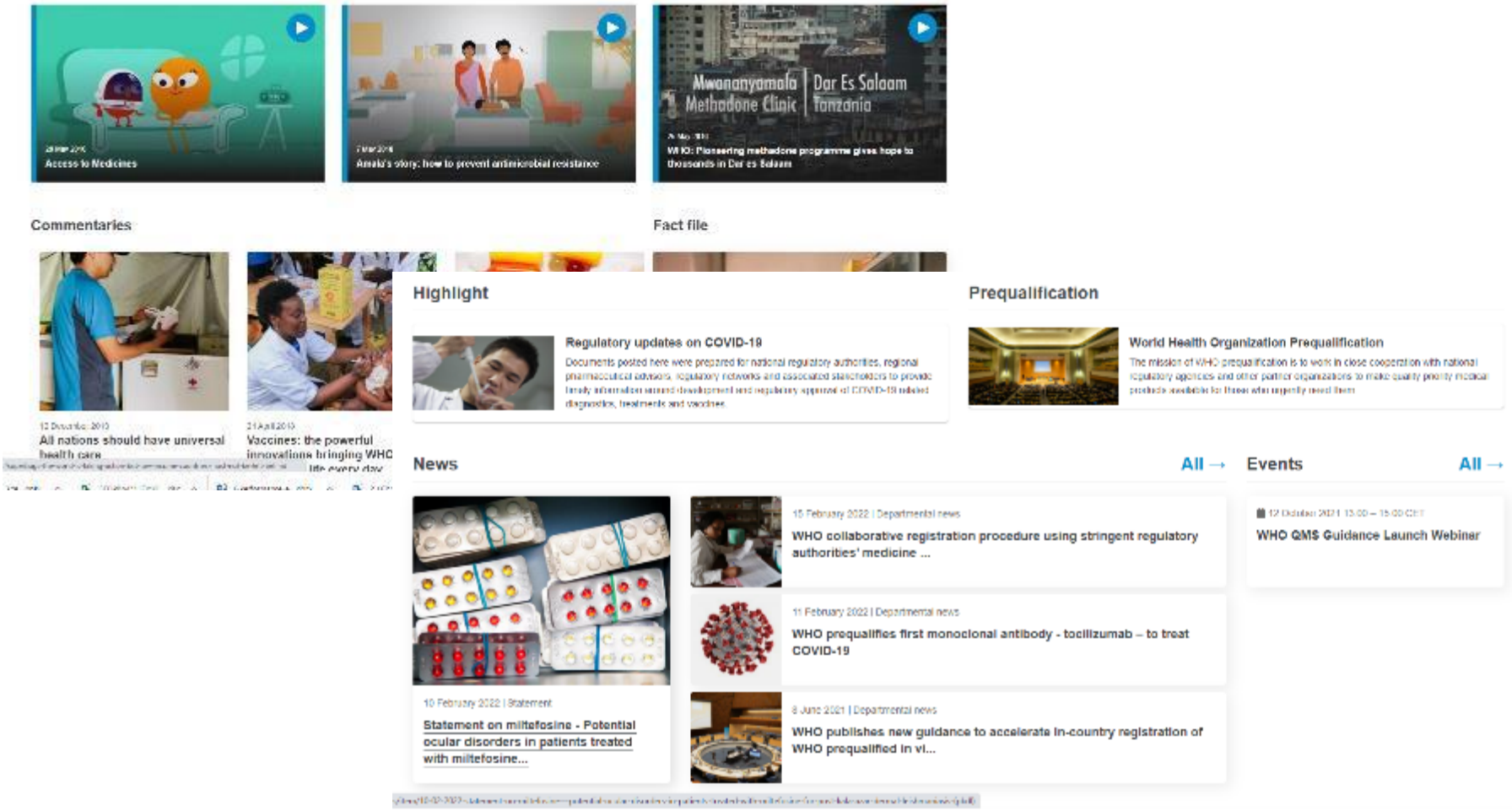
Regulatory system strengthening for medical products WHA67.20

- URGES Member States:
  - to engage in global, regional and subregional networks of national regulatory authorities, as appropriate, recognizing the importance of collaboration to pool regulatory capacities to promote greater access to quality, safe, efficacious and affordable medical products;
  - to promote international cooperation, as appropriate, for collaboration and information sharing, including through electronic platforms;
- REQUESTS the Director-General:
  - to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health 1 And, where applicable, regional economic integration organizations. WHA67.20 5 products that are the least developed, such as regulation of medical devices, including diagnostics;
  - to promote the greater participation of Member States in existing international and regional initiatives for collaboration and cooperation in accordance with WHO principles and guidelines;

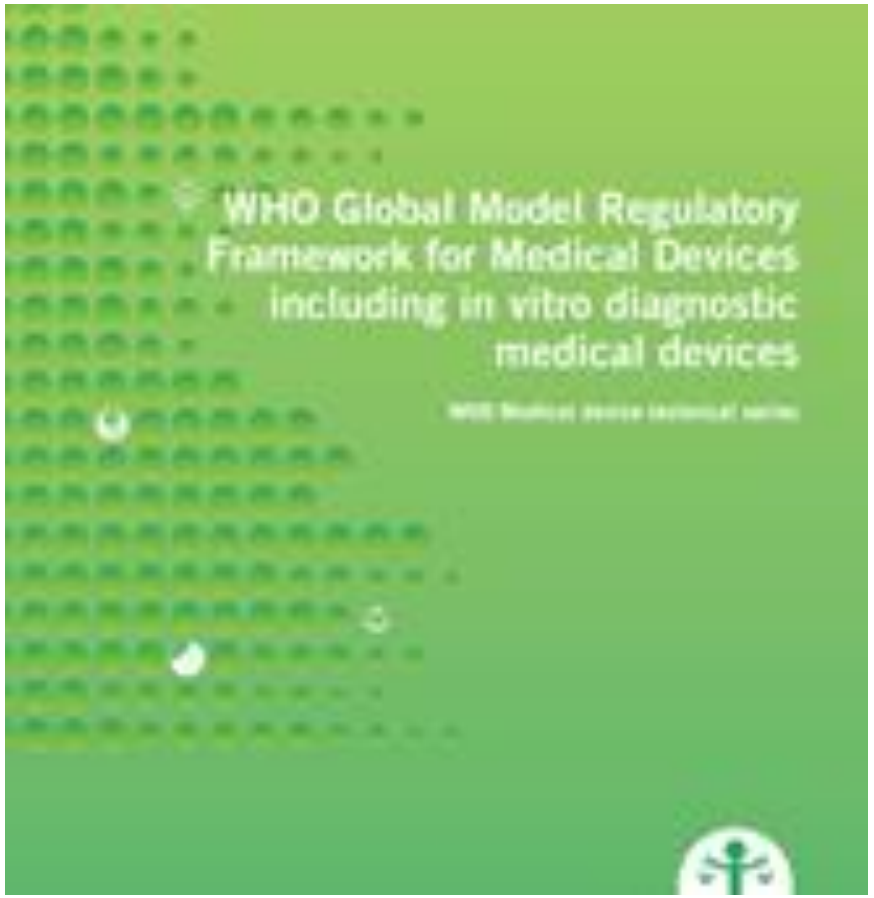
https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf

Access to medicines

https://www.who.int/health-topics/medicines#tab=tab_1



WHO work on regulatory framework



- It is being updated by WHO
- Considering all regulatory models and networks
- Reliance on other regulatory bodies, MDSAP
- Including
- Legal framework
- Premarket, postmarket
- Nomenclature, software med devices, donations, etc.
- New publication to be available end 2022

Health Technology Assessment

Trade in Pharmaceuticals and Medical Devices between the EU and Singapore - Opportunities under the EUSFTA and Beyond
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WHA 67.23 Health interventions and technology assessment in support of UHC, (24/05/2014)

Urges member states to:

- Establish national systems of health intervention and technology assessment to support UHC
- To strengthen the link between HTA , HT regulations and HT management (access and use)
- To develop national methodological and process guidelines
- Promote HITA, for health systems strengthening and UHC…
- To do networking and avoid duplication of efforts.
- Collaboration with other stakeholders ….

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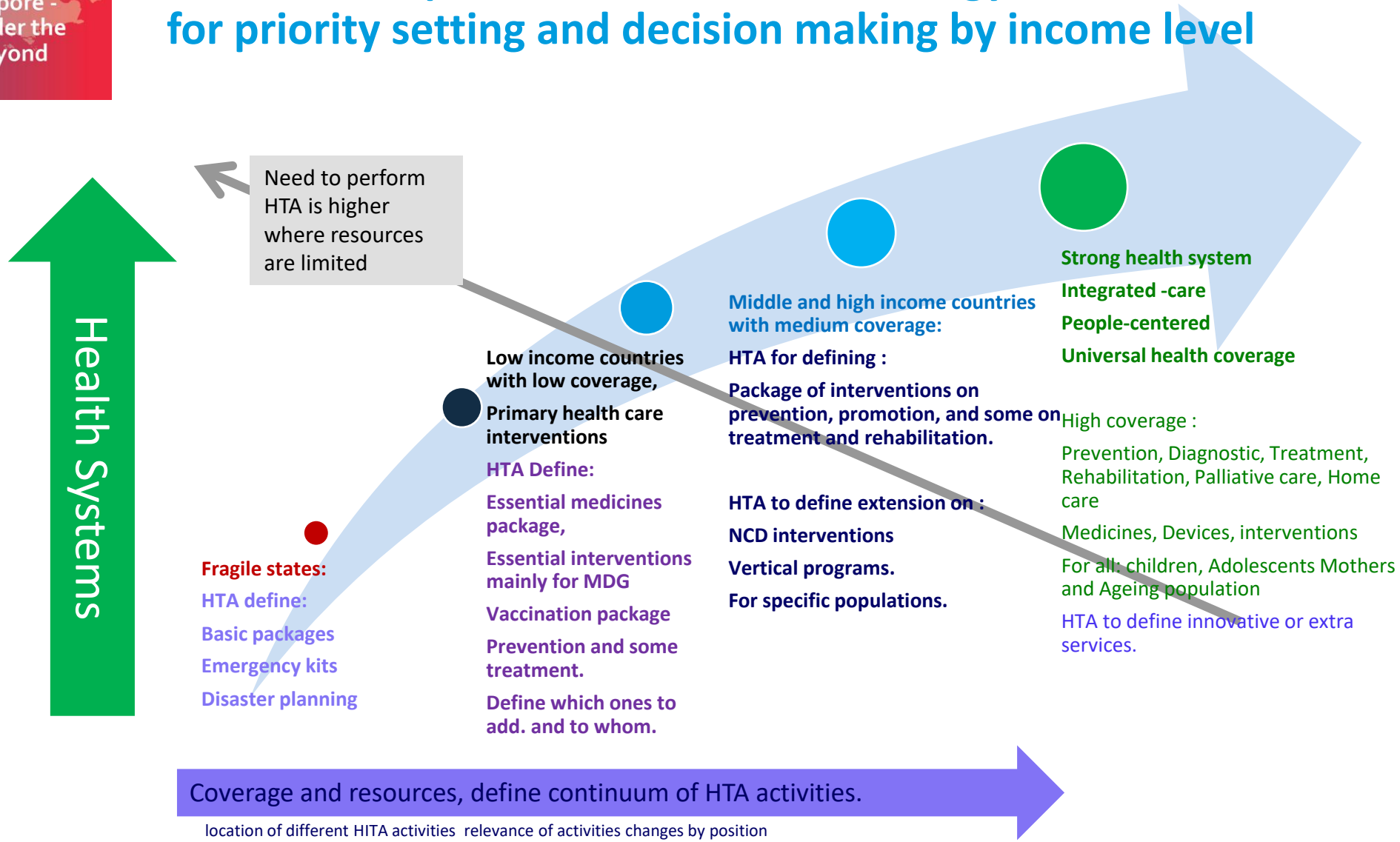
WHA 67.23
Requests the Director General of WHO:

1. to assess the status of HITA in member states
2. to raise awareness of the need for HITA
3. to integrate HITA concepts of HITA in WHO
4. provide technical support to member states
5. to ensure adequate capacity at all levels at WHO
6. To support the exchange of information and capacity building.

Continuous Spectrum of health technology assessment for priority setting and decision making by income level



The survey had five sections matching WHA67.23 request

1 UTILIZATION

Utilization of HTA observations in the public sector decision making

2 METHODOLOGY

Processes and methodology

3 CAPACITY

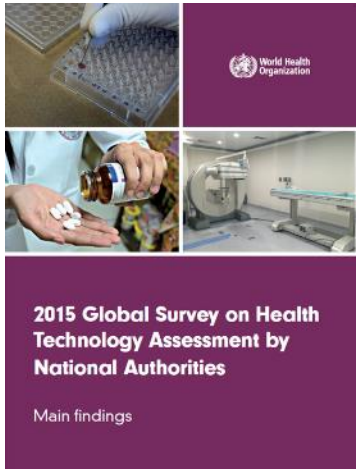
Institutional or human resources supporting HTA

4 GOVERNANCE AND LINKAGES

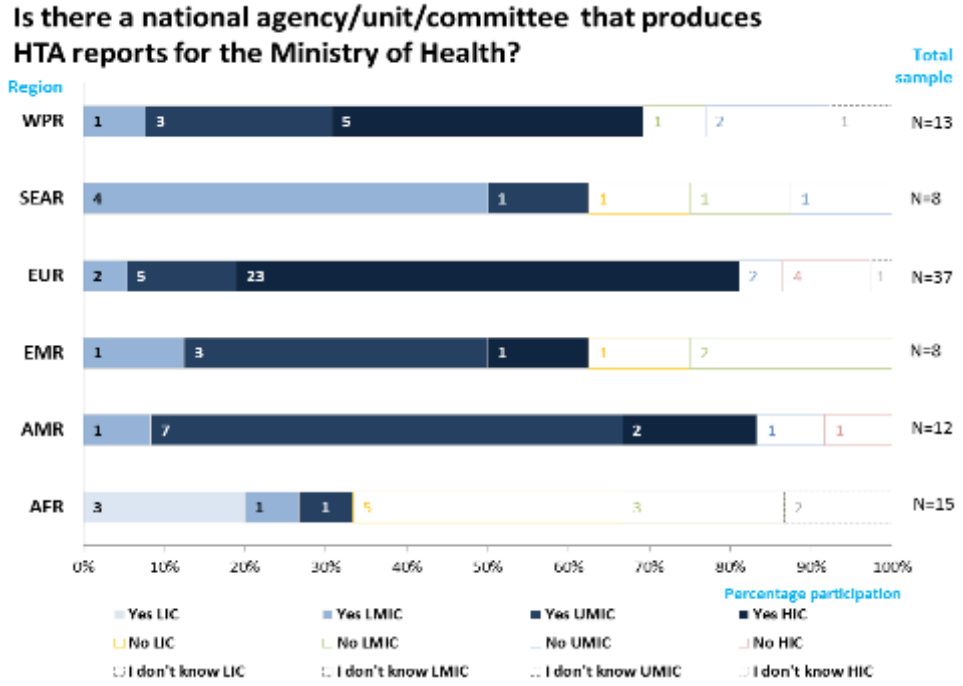
Process governance

5 IMPEDIMENTS

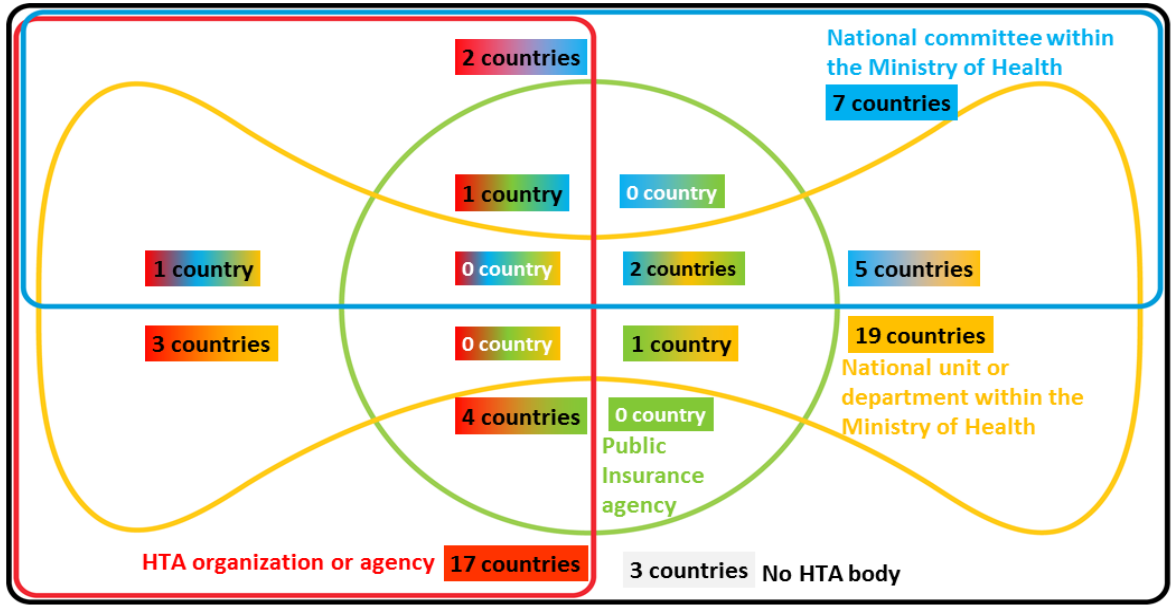
Requirements for strengthening capacity



Two in three countries had a national organization that produced HTA reports for the Ministry of Health



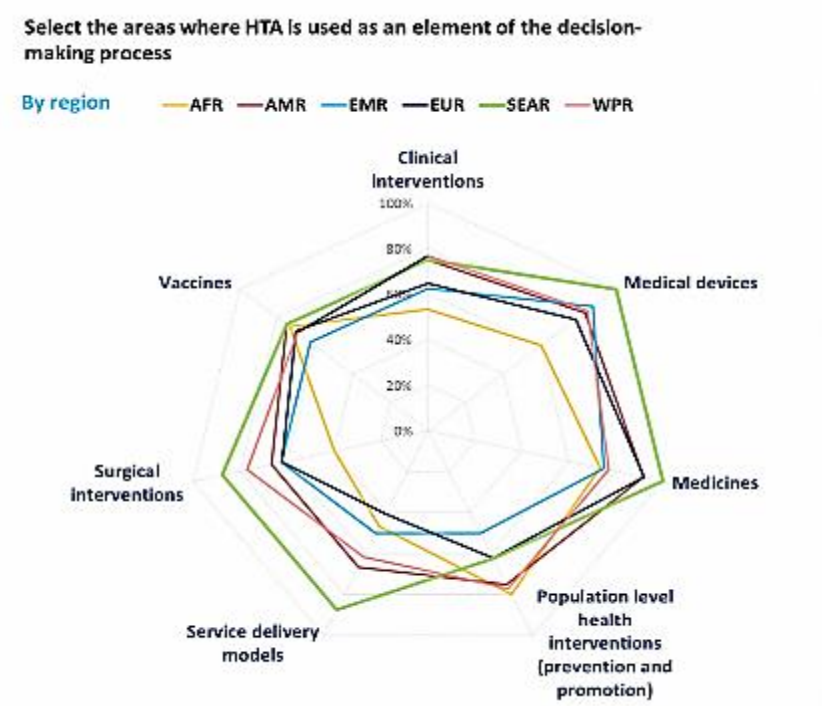
Type of National HTA agency

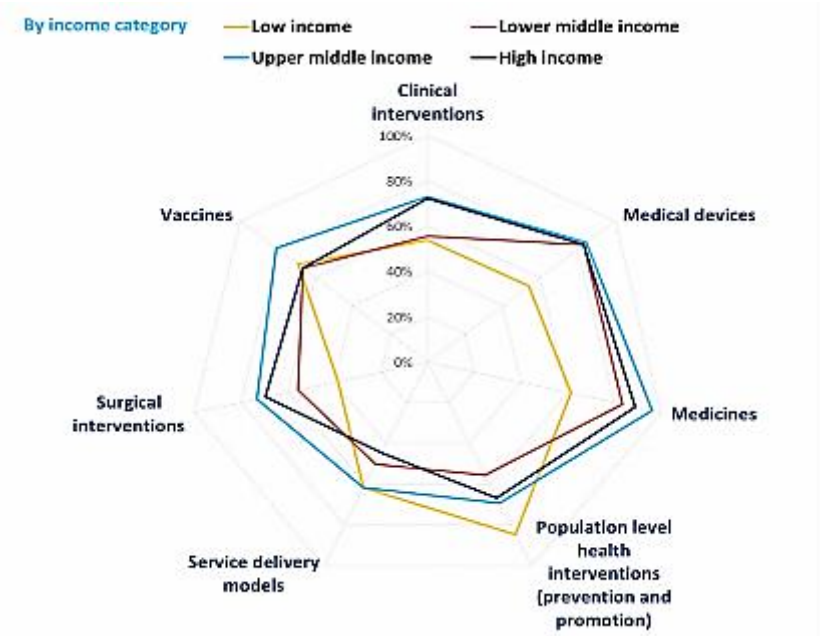


Main observations

- Europe and the American regions had proportionally more countries with a national body that produced HTA reports for the Ministry of Health.
- Most countries had a single HTA organisation/agency (17 countries) or a national unit or department within the Ministry of Health (19 countries) that produced HTA reports.

More than half of all respondents had considered observations of HTA in making decision for all types of health technologies and interventions ….



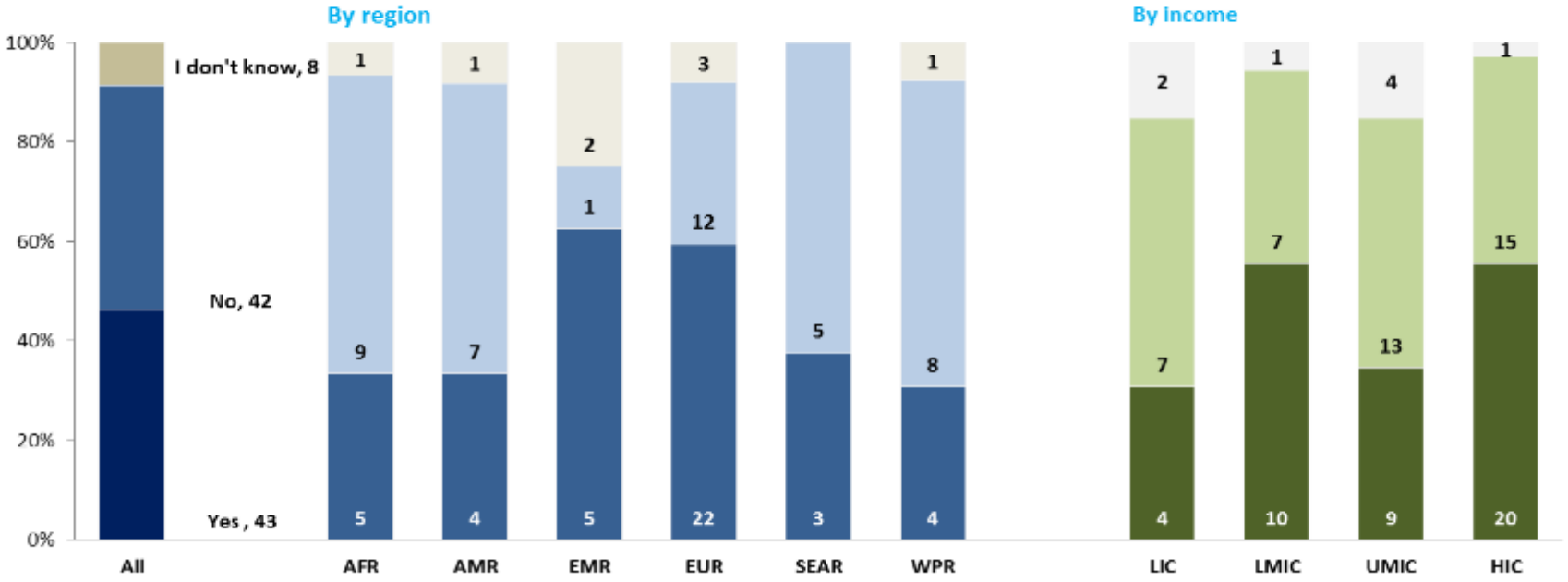


Main observations

- More than half of the respondents used HTA across all types of health technology or intervention.
- Proportionally more low income countries applied HTA to inform decision making for population level health interventions.
- Proportionally less low income countries applied HTA to inform decision for medicines, medical devices and surgical interventions.

…but less than half of the countries had legislative requirements to consider the results of HTAs

Is there a legislative requirement to consider the results of HTAs in the public health decision-making process?

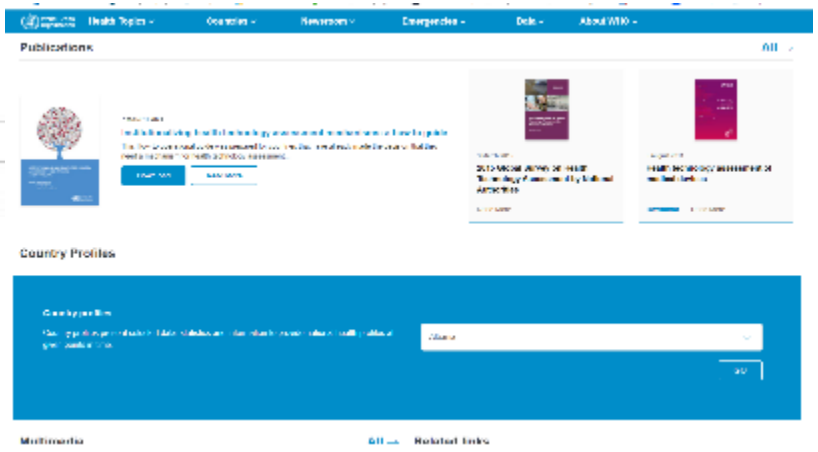


Main observations

- Respondents from EMRO (63%) and EUR (63%) indicated higher level of legislative requirements to consider the results of HTAs in health care decision making than in other regions.
- High income and low middle income countries appeared to have proportionately higher number of countries with legislative requirements.

Health technology assessment (new page in WHO)

https://www.who.int/health-topics/health-technology-assessment#tab=tab_1



Agenda

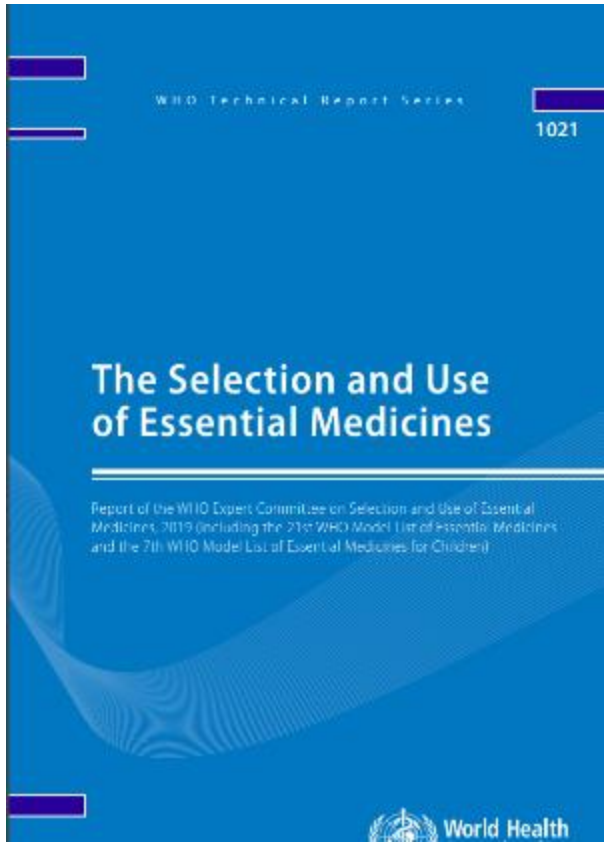
WHO ESSENTIAL AND PRIORITY LISTS

- Medicines
- Medical devices
- Assistive devices
- In vitro diagnostics

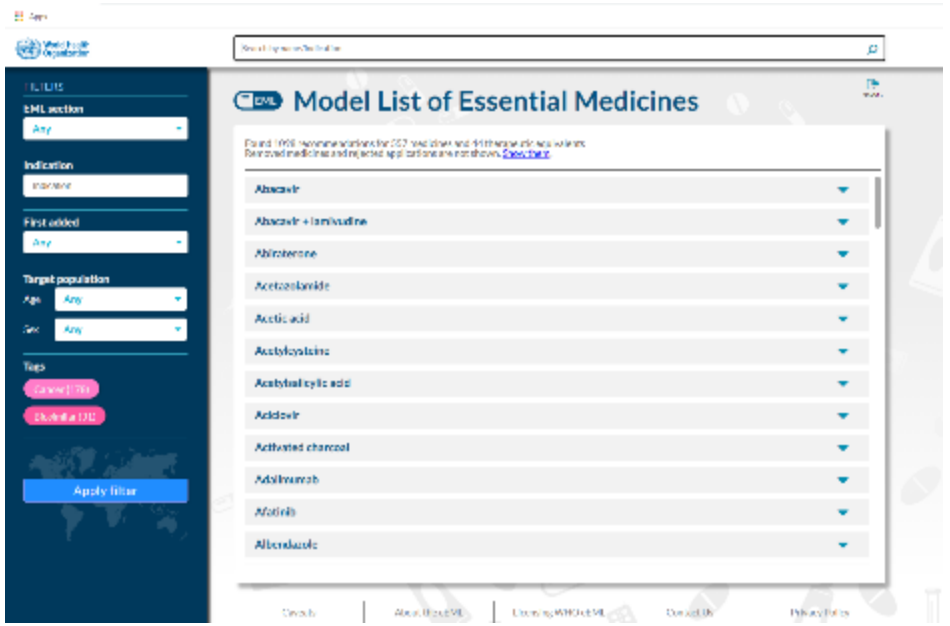
WHO Lists and process to inform development of National lists.

2022

Essential medicines List, used by many countries, include ATC, INN international codes publicly available

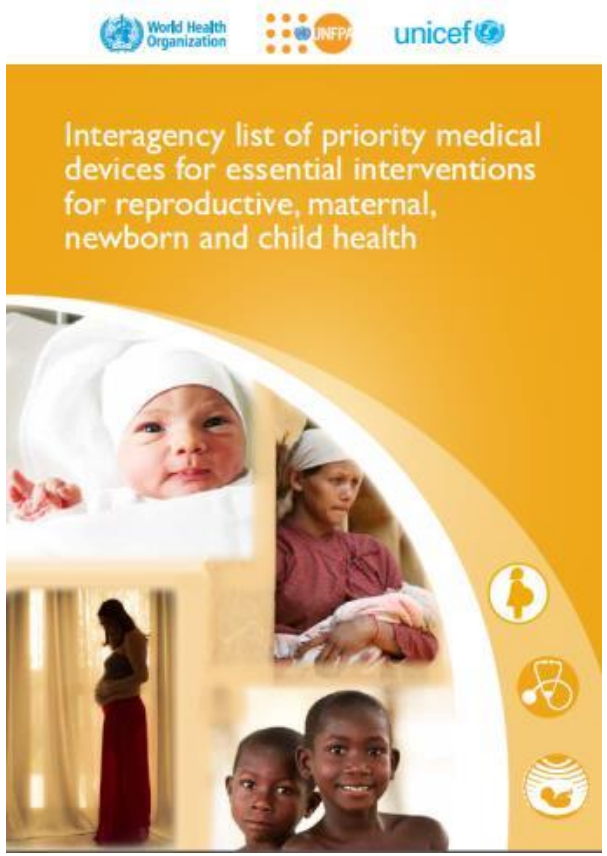


Expert committee, more 40 years ago, electronic version, selected core and complementary

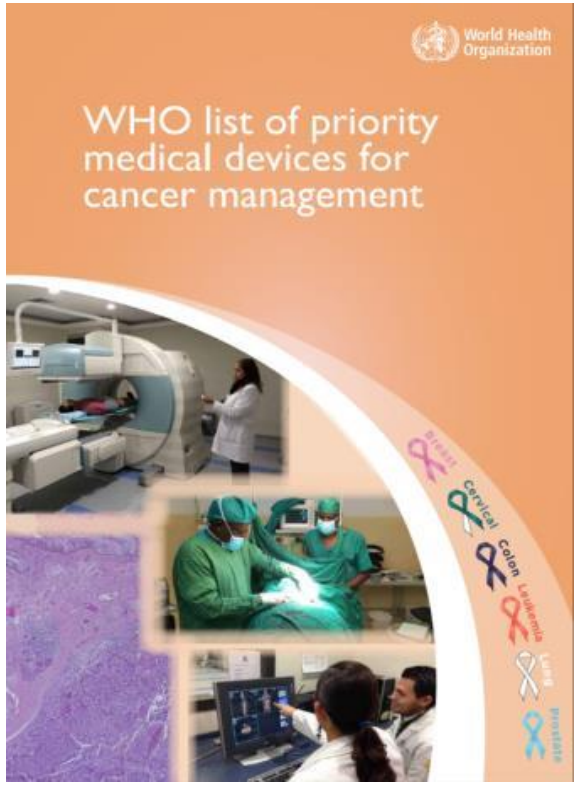


WHO Lists of Priority medical devices by interventions and levels of care (do not have internationally harmonized naming system like medicines, this hinders trade, availability, access and traceability)

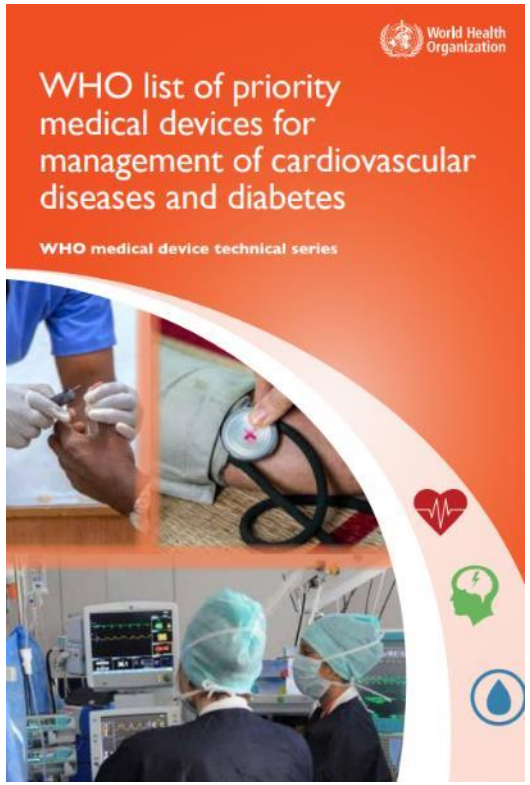
2015



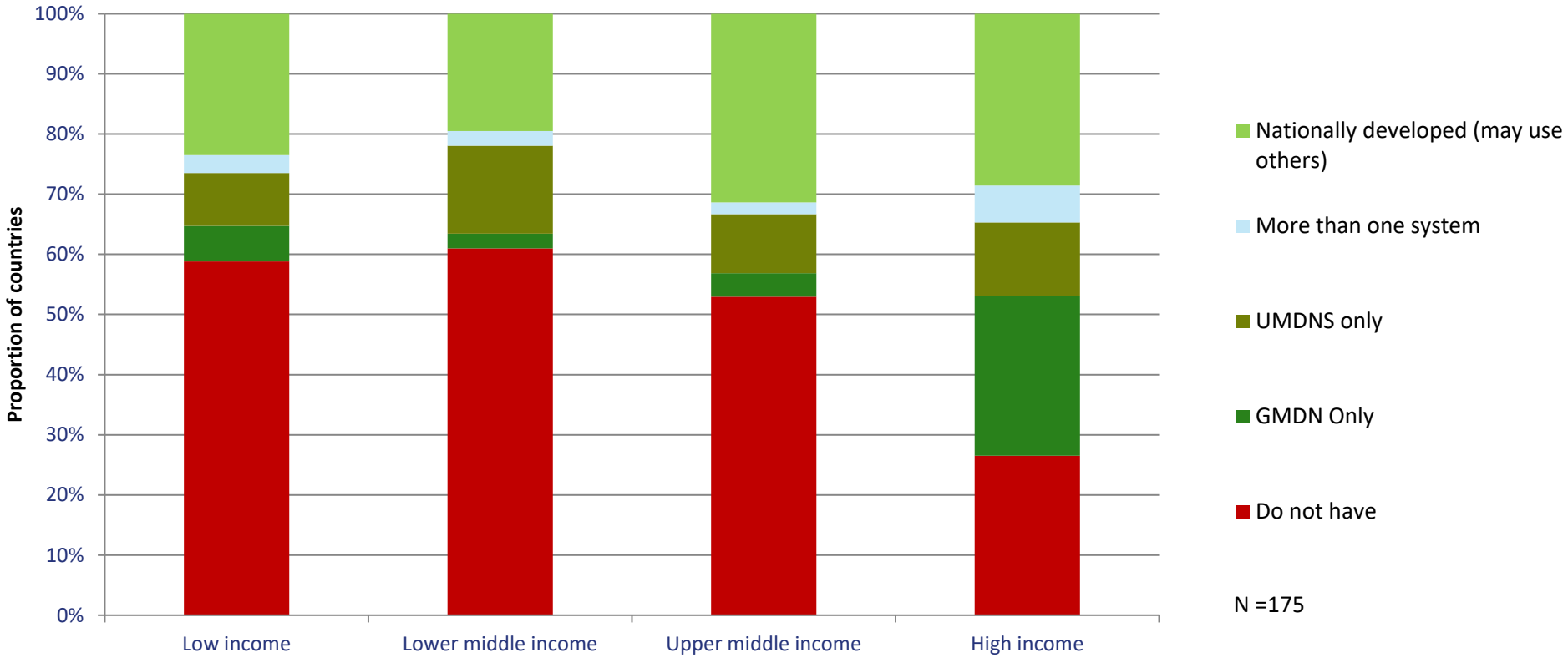
2017



2021



Country survey 2011, 2015, 2017.
National nomenclature availability in countries
Data in Global Atlas of Medical devices

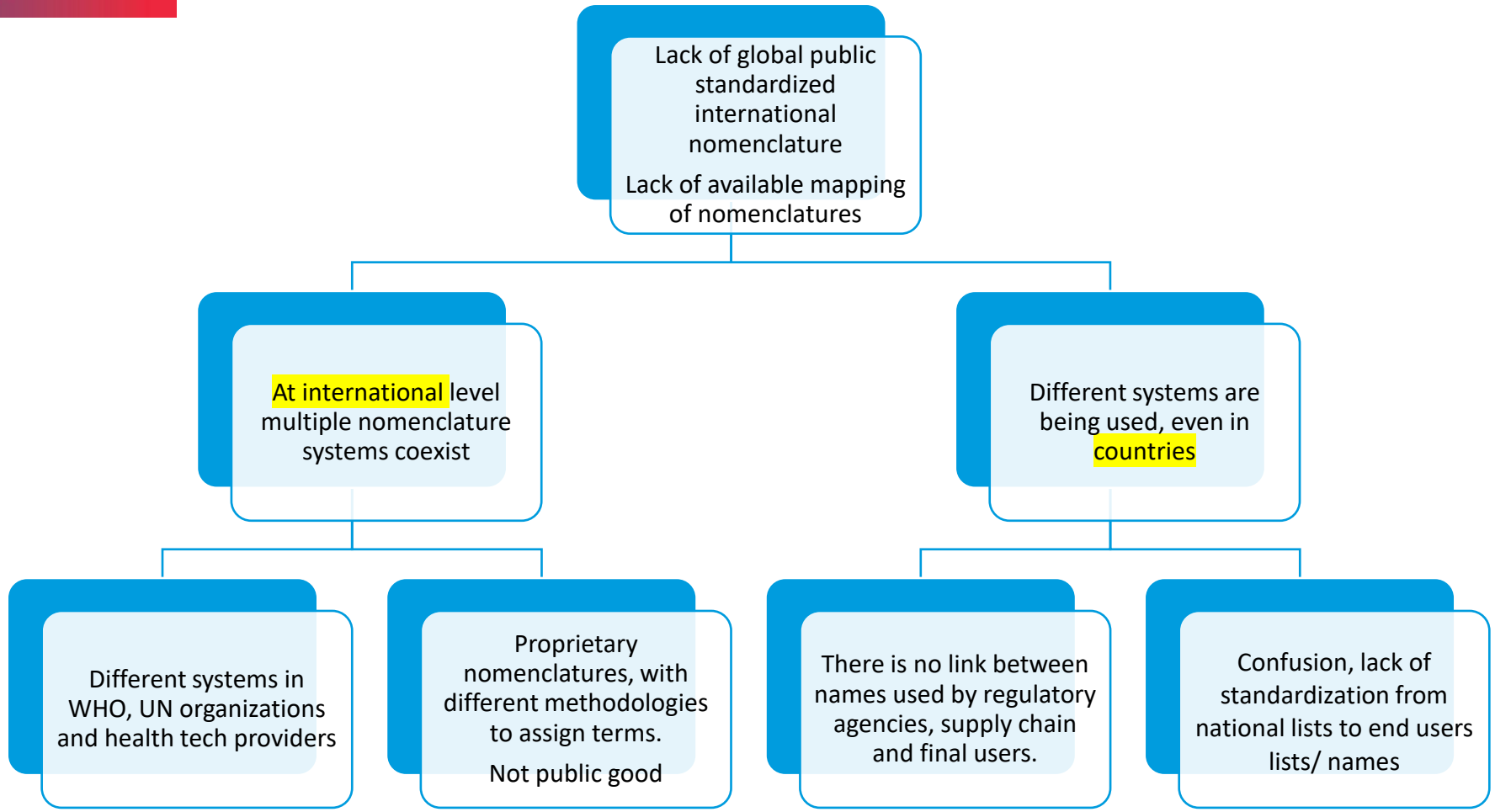


Source: WHO global atlas of medical devices, 2017
(new survey 2020 in process)

https://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/

https://icd.who.int/browse11/l-m/en

Problems of lack of international standardized nomenclature



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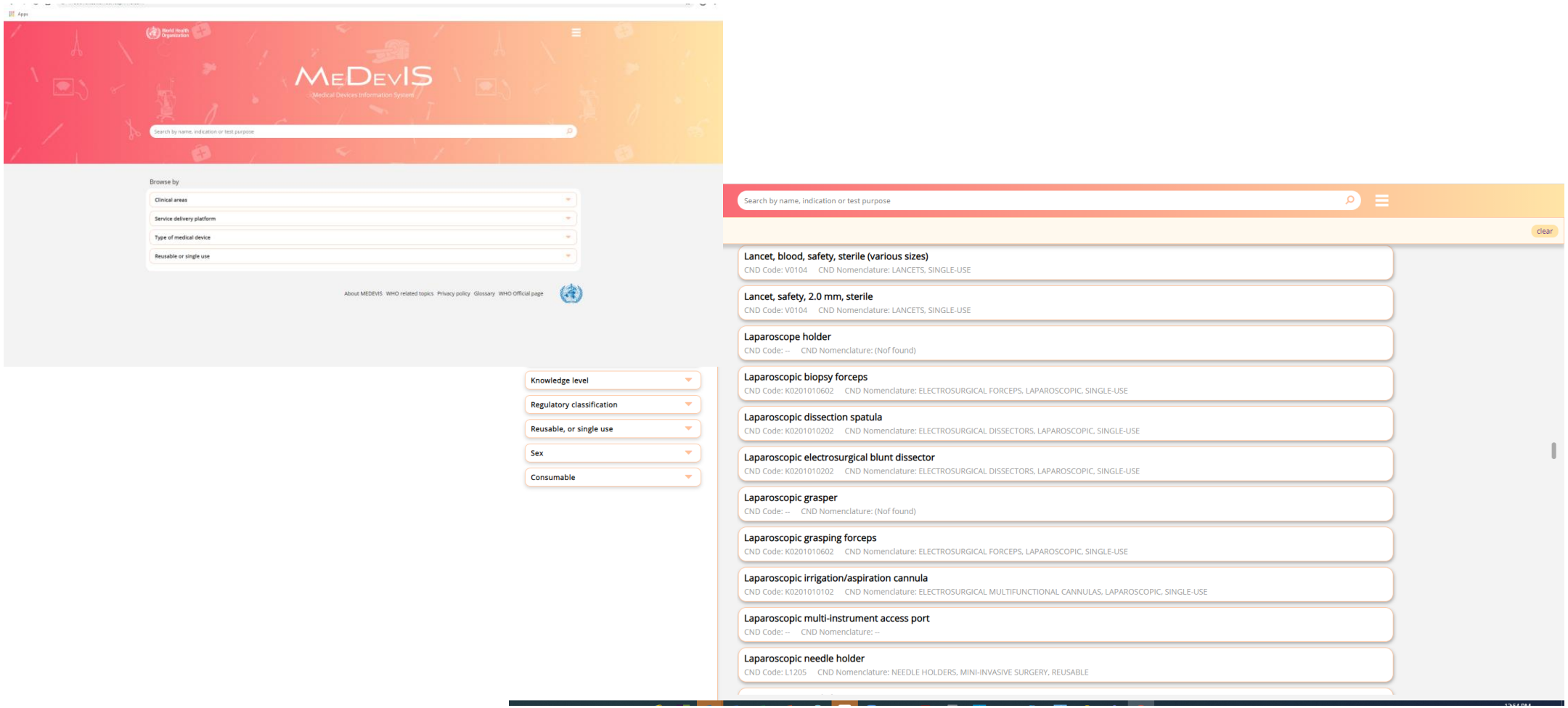
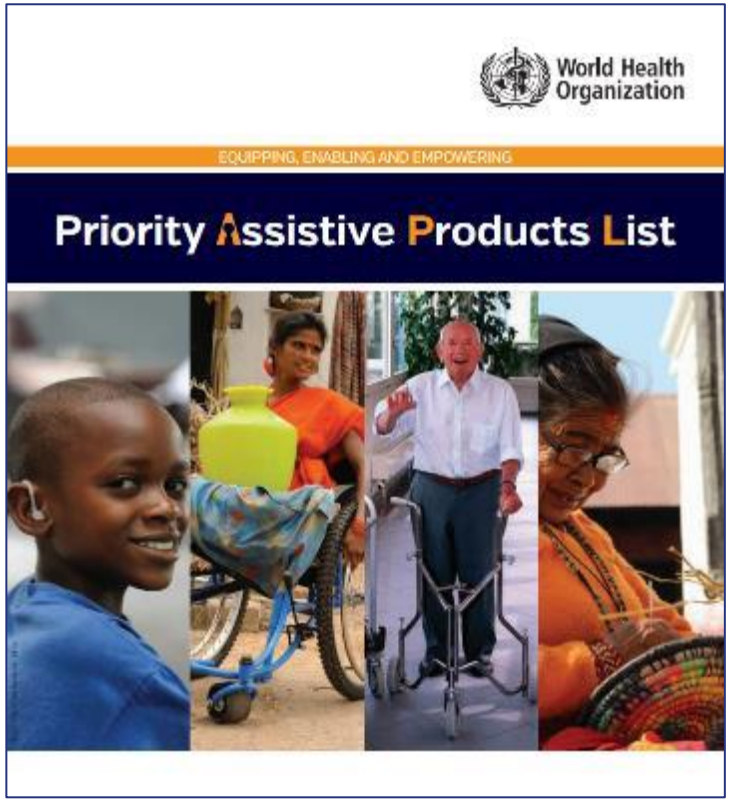
Priority medical devices information system MeDevIS …



Priority assistive products (have no international name/code)

2017 50 types



WHO Essential in vitro diagnostic list: 2018, 2019, 2020 (have no international harmonized name)

Basic test characteristics

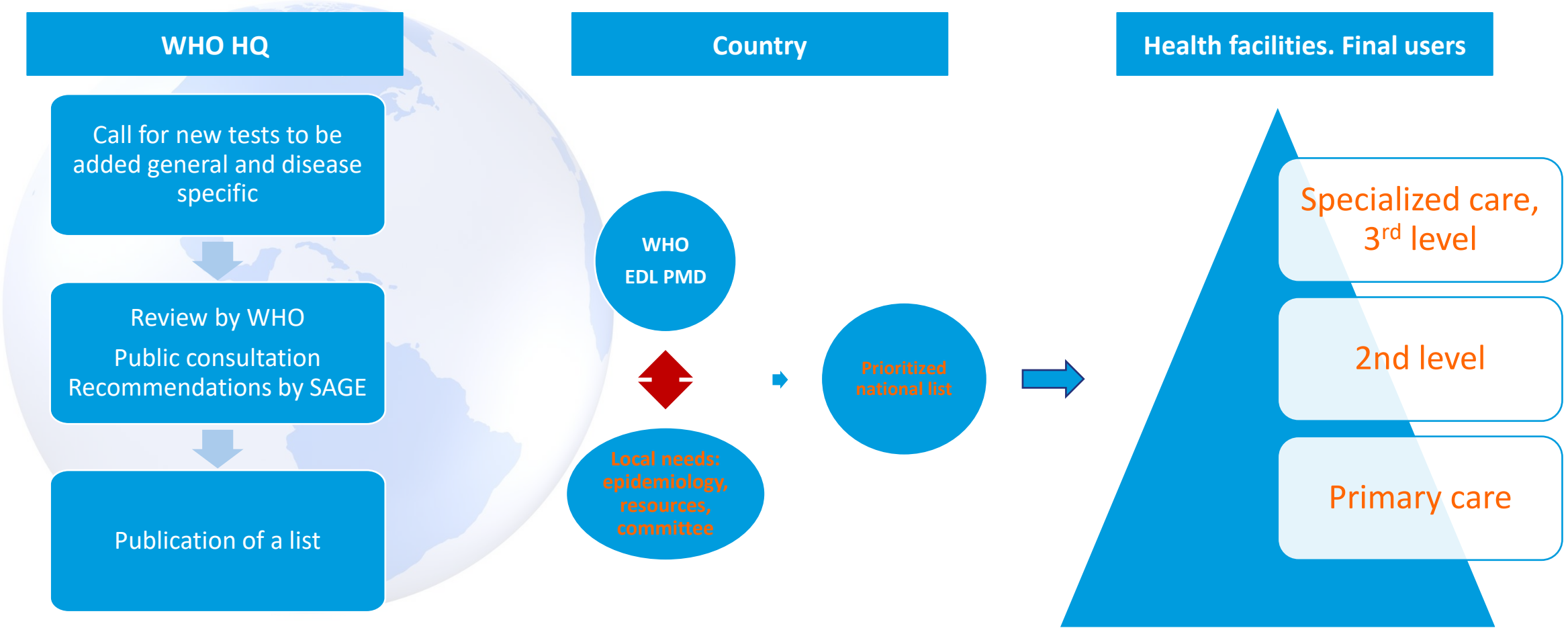
- Test purpose
- Test format
- Specimen types
- Equipment required
- Regulatory status
- Global availability
- Price per test range
- Instrument price range

Ethics, equity and human rights issues
Evidence for clinical usefulness and impact
Evidence for economic impact and/or cost–effectiveness

E-EDL

EDL secretariat

Global Implementation: From WHO tools: EDL & PMD to access of MD & IVDs at country level



Conclusions

WHO role is to increase access to health products of good quality and that they become affordable and available to all that need them.

It becomes indispensable to have harmonization, reliance, international standards compliance.

WHO develops norms and standards for health products:

- medicines, vaccines,
- assistive and medical devices and in vitro diagnostics

Based on evidence and expert groups.

These lists should be used to support universal health coverage, emergencies and well being of local population.

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Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

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EDL website:
http://www.who.int/medical_devices/diagnostics/Selection_in-vitro_diagnostics/en/